

**IN THE UNITED STATES DISTRICT COURT FOR
THE MIDDLE DISTRICT OF TENNESSEE
AT NASHVILLE**

IN RE:)	
)	
AREDIA[®] AND ZOMETA[®] PRODUCTS)	
LIABILITY LITIGATION)	No. 3:06-MD-1760
)	
(MDL No. 1760))	JUDGE CAMPBELL
)	
This Document Relates To:)	MAGISTRATE JUDGE BROWN
)	
ALL CASES)	
)	

**NOVARTIS PHARMACEUTICALS CORPORATION'S
OPPOSITION TO PLAINTIFFS' MOTION FOR SUGGESTION OF REMAND**

Having championed the creation of this MDL over NPC's objection, the Plaintiffs' Steering Committee ("PSC") now asks this Court to change course midstream, to abandon the processes established by the Court to manage pretrial discovery and other proceedings, and to flood remand courts with hundreds of cases that are not remotely trial-ready. *See* Pls.' Mot. for Suggestion of Remand ("Pls.' Mem.") 1, ECF No. 3675 (seeking remand of all 540 cases pending in this MDL or, in the alternative, remand of approximately 360 cases involving living plaintiffs). The PSC suggests that but for the MDL, plaintiffs would get their day in court sooner. But the unfortunate fact that most plaintiffs in this MDL suffer from metastatic cancer that threatens their life expectancy is a fact the PSC members knew when they sought this MDL. Similarly, the fact that MDL litigation often takes years to produce trials in remand courts is a reality of the complex nature of consolidated litigation. Indeed, when NPC opposed the creation of the MDL on the basis that, *inter alia*, the coordination process would delay the initial trials, current PSC member Robert Germany agreed stating that in his experience it took more than four years for the first case to be remanded from an MDL for trial. *See* 3/30/06 JPML Hr'g Tr. 18-19

(Ex. 1). Judged against Mr. Germany's experience and using only cases remanded for trial as the measure of achievement, this MDL has operated with great efficiency, remanding five cases for trial in September 2009 and a sixth trial case in November 2009. *See* 9/25/09 JPML Conditional Remand Order, ECF No. 2880 (remanding the *Hogan, Brodie, Fussman, Forman, and Deutsch* cases for trial); 11/6/09 JPML Conditional Remand Order, ECF No. 2936 (remanding the *White* case for trial). Three remanded cases are scheduled for trial within the next nine months – *Fussman* (November 2010), *White* (April 2011), and *Brodie* (July 2011), and three additional remanded cases – *Hogan, Forman, and Deutsch* – are in pretrial status in New York.¹

Trial scheduling in remand courts is of course uncertain and beyond the jurisdictional purview of this Court. There is simply no evidence, however, that dismantling the MDL would result in a fairer adjudication process or even quicker trials for plaintiffs. Instead, the dramatic shift in the PSC's strategy with respect to the MDL must be grounded in a belief that the chaos ensured by the simultaneous (and premature) remand of hundreds of cases will increase settlement leverage and allow the PSC greater ability to hand pick the cases it wishes to bring to trial without the inconvenience of establishing case *bona fides* and completing discovery as contemplated by processes ***previously agreed to by the parties*** as part of this MDL. This Court should not countenance the PSC's blatant gamesmanship. It makes little sense to invest substantial judicial and other resources to set up an MDL proceeding for the management of coordinated discovery and pretrial proceedings, only to abandon that effort midstream in favor of

¹ This litigation has matured such that the MDL process will produce regular paced trials in various federal district courts beginning November 2010 – exactly consistent with the objectives of “coordinated” mass proceedings. Parallel litigation is ongoing in the state court system, primarily through a coordinated proceeding in New Jersey, and two trials have proceeded to verdict in the state courts, one to a defense verdict (*Bessemer v. Novartis Pharm. Corp.*, No. MID-L-1835-08-MT (N.J. Super. Ct. Law Div.)) and one to a plaintiff's verdict (*Stevens v. Novartis Pharm. Corp.*, Cause No. DV-08-100 (Mont. 4th Jud. Dist. Ct.), *on appeal*, Case No. DA 10-0029 (Mont.)).

a chaotic remand of hundreds of cases. Such a remand would be unprecedented and is plainly unwarranted here, where the work of the MDL Court remains ongoing.

Plaintiffs have not met their burden to show “good cause” for this extraordinary request. The PSC asserts that the MDL Court’s “role under § 1407(a) has ended” (Pls.’ Mem. 1), but the JPML’s directive that “[c]entralization under Section 1407 is necessary [in this litigation] in order to eliminate duplicative discovery; prevent inconsistent pretrial rulings; and conserve the resources of the parties, their counsel, and the judiciary” remains as true today as at the MDL’s inception. *See* 4/19/06 JPML Transfer Order 2, ECF No. 1. In advocating massive remand, the PSC points to the significant generic discovery against NPC already completed, but the MDL Court’s role consists of more than supervising discovery against the defendant. For example, the MDL Court serves to weed out and dismiss cases that are not trial worthy. Exactly as contemplated by the statute, this Court has presided over the disposition of 65 cases as of this writing – more than 10% of the peak MDL case inventory (*see* App. 1) – based on product identification grounds,² substantive failings, failure to prosecute, and other recurring issues. Even within the confines of the MDL, plaintiffs’ counsel have attempted to work around the Court’s guidance on these issues, *see, e.g.*, 4/12/10 Mem. Op. 2, ECF No. 3230 (granting NPC’s motions for summary judgment as to claims of foreign plaintiffs and stating that “[t]he Court finds Plaintiffs’ position on these Motions to be astounding, given the prior Orders of this Court and the Sixth Circuit Court of Appeals”). Abandoning the MDL now would facilitate filing of cases on behalf of plaintiffs whose claims are not viable under prior orders of this Court.

Moreover, the Court has crafted an ongoing procedure – in general, *per agreement of the parties* – to ensure that parties fulfill their initial discovery and disclosure obligations in an

² 174 plaintiffs in *In re Pamidronate Prods. Liab. Litig.*, MDL No. 2120 also have pending claims against NPC in this MDL. Most of those plaintiffs have yet to provide any or adequate product identification submissions to NPC.

efficient manner (*see* Case Management Order, ECF No. 89), and the Court continues to coordinate discovery and to resolve discovery disputes across cases. The MDL Court also has an ongoing and key role in staging the caseload to maximize fairness to the parties. Thus the Court has worked to spread cases to different jurisdictions and different plaintiffs' firms as each "wave" of cases has proceeded. The PSC would have this Court believe that these functions can be performed just as well or better by 43 different federal district courts that lack this Court's experience with the unique issues in this litigation, but it is hard to envision how that is possible, or why the PSC has changed its mind about the utility of the MDL as a centralized proceeding to maximize efficiencies and minimize the potential for inconsistent rulings.

As discussed further below, MDL courts have rejected the same kind of remand proposal that plaintiffs present here, and this Court should continue on the course it has charted in these proceedings to manage pretrial discovery and to narrow the case inventory. *See In re Baycol Prods. Liab. Litig.*, MDL No. 143, Pretrial Order No. 149, 7 (D. Minn. Feb. 8, 2006) ("No case shall be eligible for remand to its transferor court unless . . . [c]ase-specific fact and expert discovery has been completed.") (Ex. 2); *In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig.*, MDL No. 1203, Pretrial Order No. 2984, 2003 WL 22341307, at *2-4 (E.D. Pa. Sept. 18, 2003) (denying plaintiffs' request for suggestions of remand and rejecting argument that completion of "generic discovery" renders MDL proceedings unnecessary because only case-specific discovery remains; allowing parties to seek suggestions of remand "once the pretrial process in their [i]ndividual cases, including case-specific fact and expert discovery, has been completed") (Ex. 3); *In re Wilson*, 451 F.3d 161, 163-73 (3rd Cir. 2006) (denying mandamus petition that sought the remand of *Diet Drugs* cases and discussing at length the many benefits of conducting case-specific pretrial proceedings in an

MDL, including frequent overlapping issues, involvement of same counsel and witnesses in multiple cases, and ability to terminate cases).

Finally, the PSC's charge that NPC desires to keep "live plaintiffs tied up in the MDL because as the Plaintiffs die, their claims are not as valuable" (Pls.' Mem. 12) rings quite hollow given that, for example, plaintiffs rejected as too burdensome NPC's request to work up 101 cases for the initial pool of potential trial cases. It is the plaintiffs – not NPC – that sought and obtained the benefit of a coordinated MDL proceeding. Given the investment by the parties and the Court in the MDL method of case coordination, it would be nonsensical to accede to plaintiffs request effectively to disband the MDL proceeding while work remains to be done. Any needed changes to the proceeding to achieve legitimate ends can of course be accomplished under the auspices of the MDL itself, but this Court should not sanction an end run around procedures established by the Court and the parties for phased discovery work up and case selection for remand and eventual trial.

ARGUMENT

Plaintiffs are required to show "good cause" for remand prior to the conclusion of pretrial proceedings. *See, e.g., In re Integrated Res, Inc. Real Estate Ltd. P'ships Sec. Litig.*, 851 F. Supp. 556, 562 (S.D.N.Y. 1994) ("The Panel has made it clear that it will 'remand an action . . . prior to completed pretrial proceedings only upon a showing of good cause.'"); *In re CBS Color Tube Patent Litig.*, 342 F. Supp. 1403, 1405 (J.P.M.L. 1972) ("We remand an action prior to the completion of pretrial proceedings only upon a showing of good cause."). Remand is not appropriate if continued consolidation will "eliminate duplicative discovery, prevent inconsistent pretrial rulings, and conserve the resources of the parties, their counsel and the judiciary." *See, e.g., In re Silica Prods. Liab. Litig.*, 398 F. Supp. 2d 563, 668 (S.D. Tex. 2005) (citing *In re*

Heritage Bonds Litig., 217 F. Supp. 2d 1369, 1370 (J.P.M.L. 2002)). Because these benefits still exist in this MDL, the Court should deny plaintiffs' motion for a suggestion of remand.

I. Plaintiffs Cannot Show Good Cause For Remand Because The Benefits Of The MDL Still Exist.

The Court should reject plaintiffs' narrow view of the role and benefits of the MDL court. "[T]he test is not whether proceedings on issues common to all cases have concluded; it is whether the issues overlap, either with MDL cases that have already concluded or those currently pending." *In re Wilson*, 451 F.3d at 170. Moreover, "the overlapping issues do not necessarily need to touch the petitioners' particular cases." *Id.*; *see also United States ex rel. Hockett v. Columbia/HCA Healthcare Corp.*, 498 F. Supp. 2d 25, 37 (D.D.C. 2007) ("[C]ases may be coordinated, and thus serve the purposes of the statute, even if all other cases have already been disposed of, so long as there is some 'common core' that makes it more just or efficient that the cases continue to be handled in one court or before one judge.").

This Court's prior rulings on overlapping issues and knowledge of the facts and issues in the litigation support continued coordination. *See, e.g., In re Patenaude*, 210 F.3d 135, 144 (3rd Cir. 2000) (finding a basis for coordination where "overlapping issues 'ha[ve] been considered'" and stating that "it is not necessary that common issues are being contemporaneously addressed"); *In re Merscorp Inc. et al., Real Estate Settlement Procedures (RESPA) Litig.*, 560 F. Supp. 2d 1371, 1372 (J.P.M.L. 2008) (transferring tag-along cases on the basis that the transferee court "is clearly in the best position" to apply its recent orders on overlapping issues, even though all prior MDL docket cases had previously been dismissed); *In re Baycol Prods. Litig.*, MDL No. 1431, 2008 WL 6259241, at *14 (D. Minn. Sept. 9, 2008) ("Based upon the long-term duration of the

Baycol MDL and the extensive background, expertise, and knowledge acquired by this Court over the course of this litigation, in conjunction with the fact that this Plaintiff will still benefit from participation in the MDL, Plaintiff's request for remand is denied.") (Ex. 4); *In re Helicopter Crash Near Wendle Creek, British Columbia, on August 8, 2002*, 542 F. Supp. 2d 1362, 1363 (J.P.M.L. 2008) ("the transferee judge has developed a familiarity with the allegations, issues, parties and counsel involved in this docket, which will further the expeditious resolution of the litigation taken as a whole"). Of course, centralization of pretrial decision making in the MDL Court offers the parties an important vehicle to consistent appellate rulings because the Sixth Circuit is considering dispositive rulings across many issues.³

Continued coordination of overlapping discovery and motions practice will conserve resources and reduce inconsistent pretrial rulings as envisioned by the JPML. *See, e.g., In re Bridgestone/Firestone, Inc.*, No. 1373, 2000 WL 33416573, at *2 (J.P.M.L. Oct. 24, 2000) ("Relevant discovery, including expert testimony, will overlap substantially in each action. Centralization under Section 1407 is thus necessary in order to eliminate duplicative discovery, prevent inconsistent pretrial rulings . . . , and conserve the resources of the parties, their counsel and the judiciary.") (emphasis added) (Ex. 5); *In re Microsoft Corp. Windows Operating Sys. Antitrust Litig.*, No. 1332, 2000 WL 34448877, at *2 (J.P.M.L. Apr. 25, 2000) (same) (Ex. 6); *In re Butterfield Patent Infringement*, 328 F. Supp. 513, 514 (J.P.M.L. 1970) (anticipated common motions for summary judgment provided a "compelling reason for transfer and consolidation,"

³ For example, the Sixth Circuit affirmed this Court's order granting NPC summary judgment and dismissing claims of three plaintiffs based on a Michigan statute and federal preemption principles. *See In re Aredia and Zometa Prods. Liab. Litig.*, 352 F. App'x 994 (6th Cir. 2009). One of those plaintiffs filed suit in the Eastern District of New York, another in the Southern District of New York, and the third in the Middle District of Tennessee. *Id.* at 995. If this Court had remanded all cases, those motions may have led to review of the same issue by both the Second Circuit and the Sixth Circuit, potentially leading to a circuit split in the same litigation.

including avoiding “inconsistent judicial treatment”); *In re Plumbing Fixture Cases*, 298 F. Supp. 484, 491-92 (J.P.M.L. 1968) (“The purpose of Section 1407 as shown independently by its clear language . . . makes it clear that its remedial aim is to eliminate the potential for conflicting contemporaneous pretrial rulings by coordinating district and appellate courts in multidistrict related civil actions.”); *In re Ocean Bank*, 481 F. Supp. 2d 892, 899 (N.D. Ill. 2007) (“MDL litigation is designed to streamline complex litigation by, in part, having one court rule on issues that would otherwise come before multiple courts”); *In re IBM Peripheral EDP Devices Antitrust Litig.*, 407 F. Supp. 254, 256 (J.P.M.L. 1976) (“In his supervisory role, [the MDL judge] is in a unique position to determine how the litigation can best proceed to insure the maximum [e]fficiency for all parties and the judiciary.”).

The Manual for Complex Litigation recognizes that the MDL court’s functions include “terminat[ing] actions by ruling on motions to dismiss, for summary judgment, or pursuant to settlement.” Manual for Complex Litigation (4th) (“MCL”) § 20.132 (Ex. 7).

Thus, in the *Diet Drugs* litigation, the Third Circuit rejected a remand motion by plaintiffs even though generic liability discovery was complete given the MDL court’s ability to dispose of cases that involve overlapping issues. *See In re Wilson*, 451 F.3d at 166, 169-70.

The PSC posits that remand of all MDL cases will hasten trials, but that proposition is speculative at best, considering the substantial work remaining to be done before pretrial proceedings are complete and the “head start” that the MDL Court has over all other federal courts due to its familiarity with the issues presented by this litigation. What a massive remand would accomplish, however, is allowing the PSC the ability to push their desired cases to trial without “interference” from the protections afforded NPC by the MDL process.

In any large-scale, complex litigation involving lawsuits all over the country, certain individual plaintiffs may believe that it is more convenient to have all proceedings occur separately in their home districts, instead of having their claims transferred to another court for consolidated or coordinated pretrial proceedings involving hundreds of other plaintiffs. “But the Panel must weigh the interests of all the plaintiffs and all the defendants, and must consider multiple litigation as a whole in light of the purposes of [§ 1407].” *In re Library Editions of Children’s Books*, 297 F. Supp. 385, 386 (J.P.M.L. 1968); *see also In re New York City Municipal Sec. Litig.*, 439 F. Supp. 267, 270 (J.P.M.L. 1977) (same); *In re Medtronic, Inc., Implantable Defibrillators Prods. Liab. Litig.*, 408 F. Supp. 2d 1351, 1352 (J.P.M.L. 2005) (Section 1407 “ensures that pretrial proceedings will be conducted in a manner leading to the just and expeditious resolution of all actions to the overall benefit of the parties.”). With many Aredia[®]/Zometa[®] cases to consider, the JPML has repeatedly concluded that, in light of the litigation as a whole, it is convenient for the parties and witnesses – as well as just and efficient – to place all of these lawsuits before this MDL Court for coordinated or consolidated pretrial proceedings. *See, e.g.*, 4/18/06 JPML Transfer Order 1-2, ECF No. 1; 12/3/08 JPML Transfer Order 1-2, ECF No. 1919. Plaintiffs’ attempt to shift the focus away from aggregate efficiency toward the interest of any particular individual plaintiff constitutes “a worm’s eye view of Section 1407” that has been previously rejected by the JPML. *In re Library Editions*, 297 F. Supp. at 386.

More specifically, the benefits that will obtain here by denying plaintiffs’ radical motion include:

Continued Coordination of Discovery, Discovery Dispute Resolution, and Case Management Across Cases.

Mechanisms devised by the Court and the parties to streamline early discovery and case management under the auspices of the MDL continue to serve their intended goals and should not be abandoned. After the MDL was created on April 19, 2006, it took several months for the parties and Court to establish the policies and procedures that would govern this complex litigation. On June 2, 2006, the Court entered its Practice and Procedure Order (ECF No. 44), which stayed discovery proceedings and addresses appearances of counsel, filing and service of documents, designations and role of liaison counsel, coordinating joint filings, procedures of the Manual for Complex Litigation, and other issues. On July 21, 2006, the Court entered Pretrial Order #1 (ECF No. 87), which appointed the PSC and Plaintiffs' Liaison Counsel their respective responsibilities. On July 28, 2006, the Court entered the negotiated forty-two page CMO (ECF No. 89), which essentially began all cases anew. *See, e.g., id.* at 2 ("This Order vacates any prior case management or scheduling order issued by a federal court . . ."). The CMO stayed most discovery during the class certification phase of the litigation (*see id.* at 14), and addresses many issues to insure the efficient conduct of the litigation, including developing a complex document production protocol and a confidentiality order, establishing what discovery would be allowed from NPC and plaintiffs and procedures related thereto, the timing of fact and expert discovery, and consequences for failure of plaintiffs' to complete a plaintiff's fact sheet.⁴

⁴ Proposed by NPC as a mechanism to reduce the number of case-specific interrogatories required in each case, to provide information regarding the inventory of cases, and to facilitate the selection of test cases for trial, *see* 6/29/06 Hr'g Tr. 62-63 (Ex. 8), the PFS has simplified early case-specific discovery across cases and has assisted the Court and the parties in identifying cases that are not trial worthy. Under the PSC's drastic remand proposal, the PFS process would simply end in favor of uncoordinated and inefficient case-specific discovery across 43 districts.

The need and efficacy of coordinated proceedings to manage discovery remains. Even in the context of this motion, plaintiffs declined to commit to end discovery against NPC. The omission is telling: the Court may recall that plaintiffs opposed NPC's request that the Court set a deadline for the close of corporate liability discovery two years ago. *See* Resp. of PSC in Opp'n to Def.'s Mot. for a Rule 16(b) Order Setting a Deadline for the Completion of General Discovery from Defendant (hereinafter "PSC's Resp. to Rule 16(b) Mot.") (ECF No. 1458) (filed under seal on July 7, 2008). Plaintiffs argued for a phased discovery and limited remand procedure and stated that they may seek additional corporate liability discovery after the Wave I-A trials:

It should be expected that bellwether trials will highlight for the parties additional issues on which discovery needs to be conducted. Plaintiffs submit that it is not unusual for additional discovery to be required after the initial bellwether trials. This is totally consistent with the procedure in place for conducting discovery in Waves, and this procedure is recognized by the Manual as an efficient means of organizing discovery and dividing the work into manageable categories.

Id. at 5 (citing MCL § 22.8).⁵ This Court agreed with plaintiffs "that specific discovery deadlines will be set as cases are ready for trial." 9/4/08 Order 3-4, ECF No. 1594.

Centralized pretrial proceedings prevent the parties from taking 43 shots at getting their way with respect to corporate discovery, confidentiality, or other issues common to all cases. Discovery in this matter continues, and plaintiffs have not assured the Court or NPC that disputes concerning the extensive discovery this Court has overseen are resolved. NPC continues to produce records to plaintiffs on a quarterly basis. Since the entry of the negotiated and agreed to Protective and Confidentiality Order, ECF No. 100 ("Protective Order"); *see* 4/8/09 Hr'g Tr. 32 (Ex. 9), on August 15, 2006, NPC has provided responses to extensive written discovery; produced in excess of seventeen million pages of hard-copy documents, electronic documents,

⁵ NPC reserves its right to challenge whether any additional corporate discovery requests are appropriate.

and e-mail as images and in searchable format; provided an electronically searchable index of the extremely lengthy New Drug Applications for Aredia[®] and Zometa[®]; and prepared a privilege log. Thus, issues could arise that reach across 43 plus jurisdictions and require the attention of over 43 judges, as well as magistrate judges, if remand is granted, imposing a great burden on the parties and courts, in addition to risking inconsistent rulings.

Allowing this MDL Court to resolve discovery disputes that arise prevents inconsistent rulings and conserves the resources of the parties and courts. There are also aggregate efficiencies to conducting case-specific discovery waves in the MDL. Instead of requiring 43 plus courts to set pretrial schedules that may conflict, this Court has been able to create one schedule per group of cases with common deadlines. As explained by one plaintiff in seeking the creation of this MDL, “[e]ven assuming good will among counsel, coordinating extensive discovery in dozens of cases, on behalf of numerous plaintiffs, with counsel spread out around the country is very difficult and requires a court’s attention.” *See* Pls.’ Reply Mem. of Law in Further Support of Her Motion for Multidistrict Transfer 10 (Ex. 10). That was when there were only 35 cases, *see* 4/18/06 JPML Transfer Order 1, not the 540 currently pending in the MDL. The PSC has argued to this Court that waves of discovery provide “an efficient means of organizing discovery and dividing the work into manageable categories,” PSC’s Resp. to Rule 16(b) Mot. 5 (citing MCL § 22.8), and they cannot deny that fact now. Case-specific discovery issues continue to arise that apply more generally, such as the Valad & Vecchione firm’s current refusal to obtain signed medical release forms from their clients even though their treating healthcare providers require them. *See, e.g.*, 9/20/10 Letter from Mr. Vecchione to Ms. Blum (Ex. 11).

Continued Narrowing of the MDL Inventory Through Dismissal of Claims That Are Not Trial Worthy Prior to Remand.

The MDL process contemplates the termination of cases in the MDL and remand of only those cases where a trial is warranted and cannot be resolved by other means. *See, e.g.*, MCL § 20.132 (recognizes MDL court's function to "terminate actions by ruling on motions to dismiss, for summary judgment, or pursuant to settlement"). The MDL is working: this Court already has dismissed 65 cases that were not appropriate for trial, including 40% of the Wave I-A cases. *See* App. 1. The PFS requirement and other CMO requirements have helped to weed out cases in which the plaintiffs are not actually committed to prosecuting their cases while also reducing the time and costs on both sides associated with numerous case-specific interrogatories and document requests.⁶ Without the MDL, plaintiffs in newly filed cases may never serve a PFS. In addition to the cases dismissed for failure to prosecute or on motions to dismiss, the Court granted NPC summary judgment on the merits in 35 cases, including 16 cases dismissed on preemption grounds, 14 cases on product identification grounds, 3 cases due to lack of admissible expert testimony on specific causation, 1 case due to insufficient exposure to Zometa[®] (2 doses), and 1 case due to insufficient proof that the plaintiff had ONJ. *See* App. 1. Many of the Court's rulings on these dispositive and non-dispositive motions overlapped and

⁶ Unfortunately, plaintiffs have too often dragged their feet on completing PFSs, requiring 40 motions by NPC pertaining to over 80 plaintiffs. *See* Docket, 3:06-cv-01760. Similarly, NPC has had to waste time that could have been spent advancing cases toward trial to remind plaintiffs to serve their complaints (4 motions to dismiss under Rule 4(m) pertaining to 24 plaintiffs), and serve suggestions of death and motions for substitution (8 motions to dismiss based on failure to comply with CMO obligations). *See id.* These PFS and CMO requirements will remain important to these proceedings as new cases are filed. In 2009, 94 new Aredia[®]/Zometa[®] cases were filed in federal court and 22 additional Aredia[®]/Zometa[®] cases have been filed so far this year in federal court. In the PSC's view, apparently even cases that have not completed the PFS process should nonetheless be remanded.

likely will arise again in the future, allowing for efficient and consistent resolution by this Court that progresses this litigation toward its conclusion.⁷

Ensuring The Parties Explore the True Value of The Case Inventory Through Manageable Dockets and Phased Remands Best Furthers the JPML's Vision of Employing Centralization to Promote the Just and Efficient Conduct of this Litigation.

This litigation has matured such that the MDL process will produce regular paced trials in various federal district courts beginning November 2010. Valuable information from initial trials that have come through the coordinated proceedings is being collected. This week, NPC won a trial in the New Jersey mass tort with the jury answering “No” to the question: “Did Novartis fail to provide an adequate warning to Mrs. Bessemer’s prescribing physician concerning the risks of jaw problems from Aredia[®] and/or Zometa[®] that Novartis either knew or should have known prior to Mrs. Bessemer discontinuing use of the drug(s)?” *See* Bloomberg, Novartis Wins New Jersey State Trial Over Jaw Injury Blamed on Bone Drugs (Oct. 6, 2010) (Ex. 13).⁸ Three remanded cases from this MDL are scheduled for trial in the next nine months – *Fussman* (November 2010), *White* (April 2011), and *Brodie* (July 2011) – and three other cases are in pretrial phases in New York. Additional cases from Wave I-B may be remanded in the near future followed by cases from Wave I-C. The Court has also selected Wave II cases and is in the process of selecting Wave III cases, so there will be an adequate supply of cases for trial.

⁷ If the Court remanded the 540 cases currently pending in the MDL, those cases would be dispersed initially among 43 different federal district courts. The Court has already ruled that many plaintiffs who filed their lawsuits at a location of their counsel’s choosing and far from their homes and treating health care providers did not file in convenient venues. *See* 3/6/08 MDL Order, ECF No. 1223; 3/6/08 MDL Mem. Op., ECF No. 1222. Plaintiffs’ remand request thus will likely lead to hundreds of venue transfer motions followed by transfer to many additional federal district courts, all an unnecessary exercise given the reality that many of these cases will not be tried. *See* 4/24/08 Hr’g Tr. 43 (Ex. 12) (THE COURT: “I don’t think anybody realistically thinks that you know, there’s 450 of these cases are gonna get tried.”); *id.* (THE COURT: “I agree having them basically ready to remand all of them, certainly to me, would be horrendously expensive.”).

⁸ *Bessemer* was a “plaintiff trial pick” and one of the first two cases teed up for trial in the New Jersey mass tort litigation. On April 1, 2010, the New Jersey state court granted NPC summary judgment in the other trial case, *Walsh v. Novartis Pharmaceuticals Corporation*, No. MID-L-6031-08-MT (N.J. Super. Ct. Law Div.) (Ex 14).

The information obtained from trials like *Bessemer* that are well prepared on both sides through appropriate discovery and due consideration by the courts of pretrial motions will provide a significant part of the foundation for evaluating and valuing the remaining inventory of cases.

The PSC's proposed remand of hundreds of untested and undiscovered cases would not serve the just and efficient conduct of this litigation, and would unnecessarily burden remand courts. This Court chose the correct approach when it determined that it will progress discovery waves "on as fast a schedule as practical," 3/19/08 MDL Order 3, ECF No. 1263, filing suggestions of remand once cases are sufficiently trial-ready to no longer benefit from MDL coordination. This approach to remand, which obviously minimizes the burden on the federal judiciary by maximizing the efficiencies of centralization, has been sanctioned by the JPML in numerous MDLs.⁹ In sum, this Court has adopted a sensible approach to management of this MDL which should continue.

⁹ The JPML has authorized phased remands in numerous MDLs, including the *Breast Implant* MDL (5,228 cases remanded over four years) and the *Bone Screw* MDL (1,251 cases remanded over 6 1/2 years). See 2009 JPML Statistical Analysis; U.S. Judicial Panel on Multidistrict Litigation, Multidistrict Litigation Terminated through September 30, 2009, available at http://www.jpml.uscourts.gov/Statistics/JPML_Terminated_Litigations-2009.pdf; see also *In re Silicone Gel Breast Implants Prods. Liab. Litig.*, MDL No. 926, Order No. 60A (N.D. Ala. May 30, 2000) (Ex. 15); *In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL No. 1014, 1997 WL 704702, at *1 (E.D. Pa. Aug. 22, 1997) (Ex. 16). Moreover, the JPML has approved phased remands of groups of MDL cases that transferee courts have intermittently deemed eligible for remand, e.g., after case-specific discovery (or some limited case-specific discovery) had been taken or some other requirements had been met. See U.S. Judicial Panel on Multidistrict Litigation, Statistical Analysis of Multidistrict Litigation 2009, available at http://www.jpml.uscourts.gov/Statistics/JPML_Statistical_Analysis_of_Multidistrict_Litigation_2009.pdf; U.S. Judicial Panel on Multidistrict Litigation, Distribution of Pending MDL Dockets, July 8, 2010, available at http://www.jpml.uscourts.gov/Pending_MDL_Dockets-July-2010.pdf; *In re Diet Drugs*, Suggestion of Remand No. 42 (E.D. Pa. Oct. 13, 2009) (Ex. 17) (only 140 cases, out of 20,172 total cases, have been remanded in *Diet Drugs* over the last nine years, with 140 cases remaining in the MDL); *In re PPA*, Final MDL Pretrial Order 11-13 (W.D. Wash. May 19, 2004) (Ex. 18) (only 488 cases, out 3,385 total cases, were remanded in *PPA* over approximately four years; a case was not considered "ripe for remand" unless all permitted discovery had been completed and the case had undergone mediation); *In re Prempro*, MDL Pretrial Order and Suggestion of Remand 8-10 (E.D. Ark. Feb. 23, 2010) (Ex. 19) (opening case-specific discovery in nearly 200 cases, and requiring at least some depositions in all cases prior to suggestion of remand in those cases).

II. Plaintiffs Cannot Show Good Cause For Remand Where The MDL Court Managed Cases Effectively and Efficiently And Any “Delay” Resulted From The PSC’s Litigation Strategies.

NPC opposed plaintiffs’ pursuit of this MDL. *See* NPC’s Mem. of Law in Opp’n to Mot. for Multidistrict Transfer (filed 2/16/06) (Ex. 20). NPC argued that the initial case workup and trials would occur more swiftly without an MDL. *See id.* at 6 (“Discovery in the four earlier-filed NPC cases is underway; the parties have exchanged written discovery, and medical records collection and document review is ongoing. Scheduling orders setting trial dates have been entered in those four cases. The first trial setting is June 2007.”) (internal citations omitted). The one plaintiffs’ lawyer who opposed an MDL, Mr. Germany, made clear that he agreed with NPC that the process of setting up an MDL would delay the initial trials. *See* 3/30/06 JPML Hr’g Tr. 18-19 (Ex. 1). Mr. Germany explained that in his experience it took over four years for the first case to be remanded from an MDL for trial. *Id.*

Established over NPC’s objection, the existence of the MDL (“if you build it, they will come”) allowed the PSC to amass 540 MDL cases over the course of the MDL to date.¹⁰ Now that the investment has been made into the MDL, “good cause” is required to remand any cases before the completion of pretrial proceedings and the benefits of the MDL still exist. *See supra* page 5. Plaintiffs should not be allowed to game the system just because the current phase of the litigation – predominately case-specific fact and expert discovery for groups of individual cases – allows NPC to obtain dismissals on the merits and prepare effectively to defend itself at trials of those cases that are not terminated in the MDL.

¹⁰ Because both general and case-specific discovery was completed for the Wave I-A cases, most of the resources were devoted in the early years of this litigation to discovery directed at NPC. NPC produced 17.4 million pages of documents and submitted to 70 depositions.

The PSC Delayed Individual Trials by Litigating Uncertifiable Class Action Lawsuits.

Although this MDL was created in April 2006, plaintiffs delayed trials by litigating uncertifiable class action lawsuits until October 2007. *See* 10/10/07 MDL Order, ECF No. 694 (denying class certification); 10/10/07 Mem. Op., ECF No. 693. As a result, as stated by plaintiffs, “[m]erits-based fact discovery did not begin until July 2, 2007.” PSC’s Resp. to Rule 16(b) Mot. 2, ECF No. 1458 (citing CMO at 39). Thus, it has only been three years since the end of the class certification proceedings and during that time, the Court has dismissed 62 cases, *see* App. 1, remanded six cases for trial, coordinated Wave I-B for which *Daubert* and summary judgment briefing is now complete, coordinated Wave I-C for which expert discovery recently closed and *Daubert* and summary judgment briefs will be filed on October 15, 2010, selected cases for Wave II discovery, and begun selecting cases for Wave III discovery.

The PSC Delayed Trials by Limiting the Number of Discovery Workup Cases.

In April 2008, NPC proposed working up 101 cases from the original Wave I cases – cases that were in the MDL at the time the CMO was entered – which would have ensured an adequate and diverse supply of trial ready cases. *See* 4/24/08 Hr’g Tr. 39 (Ms. Latimer: “Novartis believes that all of the cases that were subject to the original CMO which is 101 cases I think now Your Honor, after the Michigan cases were resolved by summary judgment recently, we think that discovery in all 101 is appropriate.”). Although the PSC now implies that NPC is responsible for delay in MDL proceedings, plaintiffs opposed NPC’s request to prepare a trial pool of 101 cases. Pls.’ Supp. to Proposal of PSC as to Am. to CMO, 7, ECF No. 1327 (stating that NPC’s proposal to workup 101 cases was “inefficient, not cost effective and defeats the purpose of having bell-wether trials”).

The PSC Delayed Remand of Wave I-A Cases by Motions to Extend Discovery Deadlines.

Plaintiffs have admitted the challenge and demands of properly preparing even small groups cases in this complex litigation, seeking extensions of deadlines during Wave I-A that delayed remand of those cases. *See, e.g.*, 9/18/08 PSC's Unopposed Motion to Amend Certain Scheduling Deadlines 1 ¶ 2, ECF No. 1610 ("The PSC has been working diligently to comply with the deadlines imposed by DE 1476; however, due to scheduling issues it is unlikely that the [expert] reports will be ready for service on September 22, 2008.").

NPC Has Not Delayed Trial Inappropriately In The Remand Courts.

Plaintiffs accuse NPC of improperly delaying trials after remand.¹¹ Plaintiffs fault NPC for filing *Daubert* motions in the remand courts. *See* Pls.' Mem. 3-4, 9-11 (complaining that the Wave I-A trial courts are taking too long to resolve *Daubert* motions that were denied as moot by this Court and too long to resolve other pretrial motions and set trial dates). However, NPC timely filed those motions in this Court pursuant to the Court's orders. Because those motions were denied as moot, NPC properly refiled them upon remand after updating them with the relevant circuit's law and any new scientific or expert-specific developments. Plaintiffs also take issue with the schedules established by the remand courts after pretrial conferences and briefing, *see* Pls.' Mem. 3-4, but the remand courts have set their schedule with full appreciation of their own dockets and an understanding of the issues that had been addressed by this Court. Plaintiffs' complaints merely highlight one example of post-remand uncertainties.

¹¹ Of course if the PSC has genuine concerns about NPC's conduct in any remanded action, those concerns should be directed to the courts that now have jurisdiction over those cases.

III. That Plaintiffs Have Metastatic Cancer Does Not Constitute Good Cause For Abandoning The MDL.

Plaintiffs contend that they want to try cases with living ONJ plaintiffs. That objective does not justify the relief requested (remand of roughly 360 cases). Not surprisingly, when two Wave I-A plaintiffs requested pretrial proceedings outside the MDL with the hope of reaching trial sooner, the JPML rejected that request as inconsistent with the aggregate efficiency and consistency goals of § 1407. *See* 12/3/08 JPML Transfer Order 1-2, ECF No. 1919. The JPML reasoned: “The plaintiffs base a significant part of their opposition to transfer on their concern that transfer will engender further delays in a litigation in which time is of the essence. We are sympathetic to this concern; however, inclusion of the present claims in MDL No. 1760 will have the salutary effect of placing all related claims in this docket before a single judge who can formulate a pretrial program that (1) prevents repetition of previously considered matters; and (2) allows pretrial proceedings with respect to any individual issues to proceed concurrently with pretrial proceedings on common issues.” 12/3/08 JPML Transfer Order 1-2. That very same reasoning compels denial of the PSC’s request for a suggestion of remand from this Court now.

Indeed, this Court has recognized the reality that given these many plaintiffs were dying from cancer when they were treated with Aredia[®] and/or Zometa[®] and when they filed these lawsuits, “there is no assurance that a Plaintiff that is alive today will be alive at the time the cases come to trial.” 12/6/07 MDL Order 2, ECF No. 944 (rejecting argument of plaintiffs that trial case selection should be limited to cases with plaintiffs who are currently alive); *see also* 12/21/07 Hr’g Tr. 13 (Ex. 21) (“THE COURT: I mean one, one of the problems quite frankly is even if you try to pick Plaintiffs that are alive now, we are talking about trial date that’s over a

year, over a year away.”). For example, the five-year survival rate from date of diagnosis for a patient with distant breast cancer, which includes Stage IV or metastatic disease, is 23%.

American Cancer Society, *Cancer Facts & Figures 2010*, 17 (Ex. 22). The five-year survival rate for a patient with distant lung cancer is 4%. *Id.* The five-year survival rate for a patient with distant prostate cancer is 31%. *Id.* The five-year survival rate for patients with multiple myeloma is 38.5%. The Leukemia & Lymphoma Society, *Myeloma Facts & Statistics*, available at http://www.leukemia-lymphoma.org/all_page.adp?item_id=6989 (Ex. 23).

Thus, plaintiffs who are diagnosed with metastatic cancer or multiple myeloma, treated with Aredia[®] and/or Zometa[®], and later develop ONJ, often are deceased when the complaints are filed or have a few months or years to live – though there is powerful evidence that their use of Zometa[®] may contribute to a longer survival time. *See* Coleman RE, et al., Zoledronic Acid Use in Cancer Patients, *Cancer* 2010, e-published in Wiley Online Library. The *White* case discussed in plaintiffs’ memorandum illustrates this point. Mr. White filed his complaint in March 2006 and died from metastatic carcinoid of the lung six months later in September 2006. *See* White Compl., 3:06-cv-00550, ECF No. 19-2; White Death Certificate, ECF No. 2312-2.¹²

In recognition that dying plaintiffs may not be alive or able to testify at the time of trial, both the Federal Rules of Civil Procedure and this Court’s CMO ensure that a dying plaintiff’s case will not be prejudiced by allowing the plaintiff to preserve his testimony through a *de bene esse* deposition and many plaintiffs have taken advantage of that opportunity in this litigation.

¹² Plaintiffs’ motion misrepresents NPC’s counsel’s comments to the Eastern District of California regarding Mr. White’s death. *See* Pls.’ Mem. 5, ¶ 25. At the trial court’s request, NPC’s counsel explained factors that went into NPC’s selection of the *White* case in Wave I-A, including the fact that California law precludes recovery of non-economic compensatory damages in survival actions. *See* 8/30/10 Hr’g Tr. 43-44 (E.D. Cal.) (Ex. 1 to Pls.’ Mem., ECF No. 3605-1). Although the PSC implies in its discussion of the *White* case that the “value” of all plaintiffs’ cases declines with the passage of time (*see* Pls.’ Mem. 5), that assertion is completely unsupported. California law on the recovery of compensatory damages in a survival action differs from the law of most states on that issue. Moreover, whether a particular jury might award greater or lesser compensatory damages in the case of a deceased versus a living plaintiff is pure conjecture.

See, e.g., Fed. R. Civ. P. 32(a)(4) (“A party may use for any purpose the deposition of a witness . . . if the court finds: (A) that the witness is dead”); CMO, 21 (“If there is a material risk that any plaintiff may become incapacitated – that is, become physically or mentally incapable of providing complete and accurate testimony – plaintiff’s counsel may take a preservation deposition of the plaintiff.”). The fact that NPC won a trial this week in the New Jersey mass tort involving a living breast cancer patient who blamed her jaw condition on Aredia[®] and Zometa[®] therapy further undercuts any claim by plaintiffs that they would be prejudiced by trying cases where the cancer patient is deceased.¹³

On the other hand, NPC has a right to complete discovery, including deposing plaintiffs and treating health care providers, in preparation for trial or motions for summary judgment that would be prejudiced if the Court granted plaintiffs’ request to contemporaneously remand some 360 cases. *See e.g.*, Fed. R. Civ. P. 26 advisory committee’s note (“The purpose of discovery is to allow a broad search for facts, the names of witnesses, or any other matters which may aid a party in the preparation or presentation of his case.”); *Epstein v. MCA, Inc.*, 54 F.3d 1422, 1423 (9th Cir. 1995) (“The Federal Rules of Civil Procedure creates a broad right of discovery because wide access to relevant facts serves the integrity and fairness of the judicial process by promoting the search for the truth.”) (internal quotation marks omitted); *Krause v. Rhodes*, 671 F.2d 212, 214 (6th Cir. 1982) (“Some four decades of practical experience have convinced this Court that the need for trial frequently disappears once both sides have a full and complete understanding of the facts.” (quoting district court opinion)). This Court chose the correct approach when it determined that the Court and the parties would progress discovery waves “on

¹³ In any event, the majority of cases currently being worked up in the MDL for priority remand involve living plaintiffs. To NPC’s knowledge, 3 of 9 Wave I-B plaintiffs are alive, 7 of 12 Wave I-C plaintiffs are alive, and 21 of 36 Wave II plaintiffs (all of which were selected by the Court) are alive. Of the pool of 24 cases currently in Wave III, 15 plaintiffs are alive, to NPC’s knowledge.

as fast a schedule as practical,” 3/19/08 MDL Order 3, ECF No. 1263, and the PSC points to no compelling reason or changed circumstance that warrants a change in the Court’s approach.

CONCLUSION

For the foregoing reasons, the Court should deny plaintiffs’ motion.

October 8, 2010

Respectfully submitted,

s/ Katharine R. Latimer
Joe G. Hollingsworth
Katharine R. Latimer
(klatimer@hollingsworthllp.com)
HOLLINGSWORTH LLP
1350 I Street, N.W.
Washington, DC 20005
(202) 898-5800
(202) 682-1639 (fax)

*Attorneys for Defendant
Novartis Pharmaceuticals Corporation*

CERTIFICATE OF SERVICE

I hereby certify that I have on this 8th day of October 2010 served a true and correct copy of the foregoing opposition, by operation of the Court's Electronic Case Filing System, on the following:

F. Dulin Kelly
Clinton L. Kelly
Kelly, Kelly & Allman
629 East Main Street
Hendersonville, TN 37075
(615) 824-3703

C. Patrick Flynn
Flynn & Radford
320 Seven Springs Way
Suite 150
Brentwood, TN 37027
(615) 370-9448

s/ Katharine R. Latimer
Katharine R. Latimer
(klatimer@hollingsworthllp.com)
HOLLINGSWORTH LLP
1350 I Street, N.W.
Washington, DC 20005
(202) 898-5800
(202) 682-1639 (fax)

*Attorneys for Defendant
Novartis Pharmaceuticals Corporation*